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09/743,612	03/13/2001	Mie Takahashi	43890-475	7340

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/743,612	Applicant(s) TAKAHASHI ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,8,10,13,15,16,18,20-23,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,10,13,15,16,18,20-23,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the claims

The Request for Continued Examination and the Preliminary Amendment filed on October 14, 2003 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, 7, 8, 10, 13, 15, 16, 18, 20-23, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 5 "capable of" is vague and indefinite. The recitation "capable of" is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison,* 69 USPQ 138. Further, for the instantly recited apparatus to work, requires that the binding reagent cause a coloration by the specific reaction with the at least one analyte. If there is no coloration then it will not work.

Claim 3 the phrase "sheet-like" is vague and indefinite. The phrase "-like" renders the claim indefinite because the claim includes elements not actually disclosed "those encompassed by"-like"), thereby rendering the scope of the claim unascertainable. See MPEP 2173.05(d). See deficiencies throughout the claims. It is recommended to change the phase "sheet-like" to ---sheet--.

Claim 3, line 4 "capable of" is vague and indefinite. The recitation "capable of" is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison,* 69 USPQ 138. Further, for the instantly recited claim to work, it requires that the reactive layer be moistened with the liquid sample. If reactive layer is not moistened with the liquid sample, then the instantly recited claim does not work. See also deficiency in claims 7, 10, 21, 22 and 27.

Claim 15, line 7 "capable of" is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison,* 69 USPQ 138. See also deficiency found in claim 27, line 7.

Claim 15, part (b) "with a substance containing said analytes" is vague and indefinite. It is unclear if applicant is referring to the liquid sample recited in the preamble of the claims or if applicant is referring to some other sample.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step wherein the labeling reagent binds to the analyte in the liquid sample. Applicant recites a labeling reagent holding layer, however the applicant fails to positively recite the labeling reagent binding to the analyte. Without a labeling reagent bound to the analyte there would be no coloration in the reactive layer and therefore there would be no signal to be detected. See also deficiency found in claim 16.

Claim 22, line 7 "with substance that contains said analytes" is vague and indefinite. It is unclear if applicant is referring to the liquid sample recited in the preamble of the claims or if applicant is referring to some other sample.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 7, 8, 15, 16, 18, 22, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al (US 6,183,972) in view of Verbeck (US 3,847,553).

Kuo et al disclose a method and device for determining the concentration of an analyte in a test fluid by immunochrmatography. Kuo et al disclose applying a sample to a test matrix (on a sample loading area), which can be in the form of a strip. Kuo et al disclose that the strip can be formed of non-bibulous or bibulous materials. Kuo et al disclose that the strip comprises a region having mobile specific binding partner for the analyte, which bears a detectable label (reagent labeling holding layer) and can react with analyte present in the fluid to form an analyte/labeled binding partner complex. Kuo et al disclose detection regions (reaction areas) which contain immobilized antibodies specific for an epitope of the analyte. These detection regions form a capture region (reaction layer)(Figure 1, #4). Kuo et al also disclose an absorbent pad (absorbtion layer) on the test strip. Kuo et al disclose detecting the labeled antibody to quantitatively determine the concentration of analyte. Kuo et al disclose the antibody label is capable of reflecting light at a predetermined wavelength and providing a reflectance spectrometer having a detector of reflectance intensity with means for moving the developed strip and detector relative to each other such as a specimen table on which the strip is placed which can be moved laterally under the read head of the detector. Kuo et al disclose that this provides in providing accurate

quantitation. Kuo et al disclose that the detector can be under microprocessor control and that desired regions can be determined and then combined with preprogrammed software to provide a monotonous dose-response curve for the quantitative determination of an analyte (col 3-5).

Kuo et al differ from the instant invention in failing to teach the reaction areas are formed so as to entirely cover the reactive layer.

Verbeck et al disclose reaction areas distributed over the entire reaction layer in a test device for determining the presence of a constituent in a liquid. Disclose that the distribution of the reaction areas in this manner provides substantially more surface area and results in more rapid wetting and quicker achievement of tests (col 2, lines 42-48).

It would have been obvious to one of ordinary skill in the art to distribute the reaction areas of Kuo et al so as to entirely cover the reaction layer because Verbeck teaches that the distribution of the reaction areas in this manner provides substantially more surface area and results in more rapid wetting and quicker achievement of tests.

The instantly recited claims recite an either/or situation. The above rejected claims of Kuo et al in view of Verbeck read on the limitation wherein said reaction areas are formed so as to entirely cover said reactive layer.

7. Claims 3, 4, 10, 13, 20, 21 and 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al and Verbeck in view of Chandler et al (US 6,271,046).

See above for teachings of Kuo et al.

Kuo et al differ from the instant invention in failing to specifically teach that the chromatographic strip includes a sheet-like solid support.

Chandler et al disclose an immunochromatographic test strip which comprises a backing sheet (sheet-like solid support). Chandler et al discloses that this backing sheet facilitates the advantage of handling of the immunchromatographic strip (col 7, lines 35-62).

It would have been obvious to one of ordinary skill in the art to incorporate a backing sheet as taught by Chandler et al into the chromatographic strip of Kuo et al because Chandler et al shows that such a backing sheet facilitates the advantage of handling the chromatographic strip.

Response to Arguments

112 2nd Rejections

8. Applicant's arguments filed October 14, 2003 concerning the 112 2nd Rejections have been fully considered but they are not persuasive.

Applicant argues that the term "sheet-like" is not indefinite and that the definition, a "sheet-like means "a surface or part of a surface in which it is possible to pass from any one point of it to any other without leaving the surface" (Webster's ninth new Collegiate dictionary, Merriam-Webster, p. 1084 (1989)). And that a person skilled in the art would have understood the scope of the claim. This is not found persuasive because as disclosed in the previous office action the phrase "-like" renders the claim indefinite because the claim includes elements not actually disclosed "those encompassed by "-like"), thereby rendering the scope of the claim unascertainable.

Further, the specification does not provide a definition or guidance for the term nor does it disclose what elements would be encompassed by the term "sheet-like".

Applicant argues that the recitation of "a labeling reagent holding layer" in claims 15 and 16 does not render the claim indefinite. It is recited as a component of the chromatographic strip. This is not found persuasive because as stated above the claim is missing an essential step for performing the process.

102 and 103 Rejections

Applicant's arguments with respect to claims 1-4, 7, 8, 10, 13, 15, 16, 18, 20-23, 26 and 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. No claims are allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tisone et al (US 6,063,339) disclose dot arrays of reagent on a test strip and discloses the importance of these arrays for providing extremely accurate and precise testing systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary Counts
Examiner
Art Unit 1641
December 17, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/22/03